K093464

1. 510(k) Summary

JAN 25 2010

Sponsor:
Synthes (USA)
1230 Wilson Drive
West Chester, PA 19380

Company Contact:
Jeffrey L. Dow, JD
Director, Clinical & Regulatory Affairs
Synthes Biomaterials
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Device Name:
Synthes RapidSorb PLUS Screw System

Classification:
Class II, 21 CFR §872.4880 – Screw, Fixation, Intraosseous

Product Code
DZL

Predicate Device:
Synthes Rapid Resorbable Fixation System (K062789)
Biomet LactoSorb® Screws (K981666)

Device Description:
Synthes' RapidSorb PLUS Screw System consists of resorbable screws and related insertion devices, including screwdrivers, drills, and taps, for use as fixation in mandibular osteotomies. The screws themselves are of various sizes and are made of Poly (L-lactide-co-Glycolide) polymer that resorbs in approximately 12 months.

RapidSorb PLUS screws are provided sterile in a pouch constructed of a clear-film outer pouch and a foil laminate inner pouch. The screws are provided sterile, for single use only, and should not be resterilized.

Intended Use:
Synthes' RapidSorb PLUS screws are indicated for use as fixation in mandibular osteotomy procedures, including:

- sagital split osteotomy
- vertical ramus osteotomy
- inferior border osteotomy
- subapical osteotomy
- genioplasty.

Substantial Equivalence:	Documentation is provided that demonstrates that the RapidSorb PLUS Screw System is substantially equivalent[1] to other legally marketed devices.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended, 21 USC §301 *et seq.*, and as applied under 21 CFR Part 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalence under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein, shall be construed as an admission against interest under the U.S. patent laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Jeffery L. Dow, JD
Director, Clinical & Regulatory Affairs
Synthes (USA)
1230 Wilson Drive
West Chester, Pennsylvania 19380

JAN 25 2010

Re: K093464
Trade/Device Name: Synthes RapidSorb PLUS Screw System
Regulation Number: 21CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or wire
Regulatory Class: II
Product Code: DZL
Dated: November 5, 2009
Received: November 6, 2009

Dear Mr. Dow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications for Use

510(k) Number (if known): Unknown K093464

Indications:

Synthes' RapidSorb PLUS screws are indicated for use as fixation in mandibular osteotomy procedures, including:

- sagital split osteotomy
- vertical ramus osteotomy
- inferior border osteotomy
- subapical osteotomy
- genioplasty.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R S Betz DDS for Dr. K. P. Mulay

Division Sign-Off)
)ivision of Anesthesiology, General Hospital
ifection Control, Dental Devices

510(k) Number: K093464